PATENT
Customer No. 22,852
Attorney Docket No. **08806.0176-00000**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
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Ola CARLSSON et al.	) Group Art Unit: 1797
	)
Application No.: 10/538,777	) Examiner: Sean Everett Conley
	)
Filed: June 10, 2005	) Confirmation No.: 5515
	)
For: A METHOD FOR PREPARING A MEDICAL SOLUTION FOR THE MANUFACTURE OF A MEDICAMENT FOR PERITONEAL DIALYSIS	)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated July 25, 2008, the Office required restriction under 35 U.S.C. § 121 between Group I, claims 1-11 and 17-25, drawn to a method of preparing a medical solution and Group II, claims 12-16 and 26-30, drawn to a solution and method of using same. Applicants provisionally elect to prosecute the claims of Group I, claims 1-11 and 17-25, with traverse.

Applicants understand that this response is timely filed without the need of an extension of time because the Office Action set a period of three months to reply to the Restriction Requirement. *See* Office Action Summary. Accordingly, a response before October 25, 2008, would not require an extension of time.

Applicants traverse the Restriction Requirement on the ground that the Office has not shown that the claims of Groups I and II do not relate to a single inventive concept under PCT rule 13.1. The Office argues that "the special technical feature of

the application is anticipated by or obvious in view of prior art." Office Action at 2. According to the Office, "the technical feature shared by the independent claims is a sterilized solution comprising one or more acetylated or deacetylated amino sugars having a pH of 2.0-5.0." *Id.* The Office states, without any explanation, that "the combination of Jonsson et al. (U.S. Patent No. 5,536,469) and the document 'Replacement of glucose with N-acetylglucosamine in peritoneal dialysis fluid-experimental study in rats' disclose the claimed special technical feature." Office Action at 2-3. Applicants respectfully disagree.

Although the Office's argument seems to be that the claims are obvious in light of the two references cited, Applicants will address both anticipation and obviousness arguments in the remarks below to clarify the record because the Office also referred to possible anticipation of the pending claims on page 2 of the Office Action.

1. The cited art does not anticipate the invention

U.S. Patent No. 5,536,469 ("*Jonsson*") does not anticipate the claimed invention because the solutions disclosed therein do not contain acetylated or deacetylated amino sugars. Rather, *Jonsson's* solutions contain "glucose or glucose-like compounds." *See*, *e.g.*, *Jonsson* at col. 1, lines 10-12.

Breborowicz et al., Replacement of glucose with N-acetylglucosamine in peritoneal dialysis fluid-experimental study in rats, *Peritoneal Dialisis International*, 21: S365-S367 (2001) ("*Breborowicz*") does not anticipate the claimed invention because the solutions disclosed therein were filter-sterilized and had a pH of 7.05. *Breborowicz* at S365, col. 2, lines 33-36. In contrast, independent claims 1 and 12 recite terminally-sterilized solutions having a pH of 2.0-5.0. Terminal sterilization "is intended to mean

that the product is sterilised in its final package by a sterilisation method involving addition of energy, e.g. heating and/or radiation." Instant specification at 6, lines 33-37. On the other hand, sterile filtration "does not secure the sterility required in [the] context [of the invention]" and is not encompassed by terminal sterilization. *Id*. at 7, lines 4-10. For at least these reasons, *Breborowicz* does not anticipate the instant invention.

2. The cited art does not render obvious the invention

One of ordinary skill in the art would not have had a reasonable expectation of success in combining *Jonsson* with *Breborowicz*

Foremost, Applicants point out that the Office has not presented any arguments as to why one of ordinary skill in the art would have combined the teachings of *Jonsson* and *Breborowicz*. Applicants remind the Office that "[t]he key to supporting any rejection under 35 U.S.C. 103 is the *clear articulation of the reason(s) why the claimed invention would have been obvious*." M.P.E.P. §2142 (emphasis added).

Nonetheless, even if one of ordinary skill in the art attempted to combine the two references, there would not have been a reasonable expectation of success in obtaining a medical solution as instantly claimed. *Jonsson* is directed to solving the problem of decomposition of glucose or glucose-like products (e.g. polymeric glucose) to toxic products in medical solutions after heat-sterilization. *See*, *e.g.*, *Jonsson* at col. 3, line 56 to col. 4, line 6. *Jonsson* teaches that heat-sterilization of glucose results in the production of undesirable toxic products. *Id*. However, *Jonsson* is completely silent as to the type of toxicity resulting from the terminal sterilization of amino sugars. *Breborowicz* does not cure this deficiency. *Breborowicz* discloses solutions comprising N-acetylglucosamine ("NAG"), which is a type of amino sugar. However, as mentioned above, the solutions in *Breborowicz* were filter-sterilized, which is a process different

from terminal sterilization. Specification at 7, lines 4-10. Therefore, *Breborowicz* also fails to provide any guidance as to the toxicity resulting from the terminal sterilization of amino sugars. Accordingly, one of ordinary skill in the art would have had no expectation that the replacement of glucose in a solution according to *Jonsson* with the amino sugar NAG disclosed in *Breborowicz* would have resulted in a viable medical solution because both references are silent regarding the toxicity associated with the terminal sterilization of amino sugars.

Indeed, to Applicants knowledge, the present application is the first publication that addresses the underlying sources of this type of toxicity. The decomposition of glucose and amino sugars takes place via completely different reactions. "NAG and other amino sugars have a major difference from glucose and glucose-like compounds by having one amino group and possibly an acetyl group coupled to the glucose ring." Specification at 4, lines 4-7. The decomposition of the acetyl group during heat sterilization increases the pH of the solution, whereas the pH of a glucose solution decreases during sterilization. *Id*. at 4, lines 7-10.

Additionally, "the decomposition pattern for an amino sugar solution during heat sterilisation follows specific Maillard reactions giving several different toxic decomposition products." *Id*. at 9, lines 22-35. Maillard reactions *do not* take place when only glucose or glucose-like compounds are present in solution. *Id*., *see also* Figures 4a to 4d, which compare the decomposition patterns of glucose-containing solutions with amino sugar-containing solutions. The number of decomposition products is much larger in the case of amino sugar-containing solutions due to the Maillard reactions. *Id*.

Applicants found that the decomposition product behind the toxicity of glucose decomposition (3.4-DG) *is not* present after the decomposition of acetylated or deacetylated amino sugars, such as NAG. *Id*. As can be seen from instant Figures 4a to 4d, the decomposition patterns for glucose-based and amino sugar-based solutions during terminal sterilization are completely different.

Based on this information, it is clear that neither *Jonsson*, directed to the heat-sterilization of *glucose*, nor *Breborowicz*, directed to the *filter-sterilization* of NAG, would have provided any guidance to one of ordinary skill in the art regarding the terminal sterilization of amino sugars. Accordingly, one of ordinary skill in the art would not have had a reasonable expectation of success when attempting the combination proposed by the Office.

For at least the foregoing reasons, the cited references do not render obvious the special technical feature of the invention. Accordingly, all claims in the application comply with the unity of invention standard and Applicants respectfully request that the present Restriction Requirement be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 22, 2008